

AMENDMENTS TO THE CLAIMS

1.3. (Cancelled)

4. (Currently amended) A ~~polyarginine-containing~~ crystal of human growth hormone (hGH), comprising polyarginine ~~complexed with said crystal of~~ and hGH, wherein said hGH is selected from the group consisting of:

- (a) the 191 amino acid sequence of native hGH; and
- (b) the 192 amino acid sequence of said 191 amino acid sequence of native hGH additionally containing an N-terminal methionine; and
~~wherein the hGH:polyarginine ratio is 12:1 to 3:1 (w/w).~~

5.6. (Cancelled)

7. (Currently amended) A ~~polyarginine-containing~~ crystal of human growth hormone (hGH), comprising polyarginine ~~complexed with said crystal of~~ and hGH, wherein said hGH is selected from the group consisting of:

- (a) the 191 amino acid sequence of native hGH; and
- (b) the 192 amino acid sequence of said 191 amino acid sequence of native hGH additionally containing an N-terminal methionine;
~~wherein the hGH:polyarginine ratio is 12:1 to 3:1 (w/w); and~~

~~wherein the crystal is characterized by a release profile such that a single administration of said crystal to a mammal provides an *in vivo* human growth hormone (hGH) serum concentration profile in said mammal having a $T_{90\%}$ - $T_{50\%}$ value higher than that provided by a single administration of the same amount of soluble human growth hormone.~~

8. (Currently amended) A ~~polyarginine-containing~~ crystal of human growth hormone (hGH), comprising polyarginine ~~complexed with said crystal of~~ and hGH, wherein said hGH is selected from the group consisting of:

- (a) the 191 amino acid sequence of native hGH; and

(b) the 192 amino acid sequence of said 191 amino acid sequence of native hGH additionally containing an N-terminal methionine;

wherein the hGH:polyarginine ratio is 12:1 to 3:1 (w/w); and

wherein the crystal is characterized by an insulin growth factor-1 (IGF-1) serum elevation profile such that a single administration of said crystal to a mammal provides an *in vivo* IGF-1 serum elevation over baseline IGF-1 level in said mammal at similar levels compared to those provided by the same amount of soluble human growth hormone (hGH) administered in more than one administration.

9. (Currently amended) A polyarginine-containing crystal of human growth hormone (hGH), comprising polyarginine complexed with said crystal of and hGH, wherein said hGH is selected from the group consisting of:

(a) the 191 amino acid sequence of native hGH; and

(b) the 192 amino acid sequence of said 191 amino acid sequence of native hGH additionally containing an N-terminal methionine;

wherein the hGH:polyarginine ratio is 12:1 to 3:1 (w/w); and

wherein the crystal is characterized by a bioavailability such that a single administration of said crystal has a relative bioavailability of at least 50% or more, as compared to that of an identical dose or lower dose of soluble human growth hormone (hGH) delivered via the same administrative route, wherein said bioavailability is measured by area under curve (AUC) of total *in vivo* hGH serum concentration for said soluble hGH and said hGH crystal.

10. (Previously presented) The crystal according to claim 7 or 8, wherein said mammal is a human.

11.-16. (Canceled)

17. (Currently amended) [[A]] The composition comprising the crystal according to claim 4, 7, 8, or 9, and further comprising an additional excipient.

18. (Canceled)

19. (Currently amended) The composition according to claim 17, wherein said additional excipient is selected from the group consisting of amino acid[[s]], a salt[[s]], an alcohol[[s]], a carbohydrate[[s]], a protein[[s]], a lipid[[s]], a surfactant[[s]], a polymer[[s]], a polyamino acid[[s]] and mixtures thereof.

20. (Currently amended) The composition according to claim 17, wherein said additional excipient is selected from the group consisting of[[::]] protamine, polyvinylalcohol, cyclodextrin[[s]], dextran[[s]], calcium gluconate, polyamino acid[[s]], polyethylene glycol, a dendrimer[[s]], polyorthinine, polyethyleneimine, chitosan and mixtures thereof.

21. (Currently amended) The composition according to claim 20, wherein said additional excipient is selected from the group consisting of: protamine, polyarginine, polyethylene glycol and mixtures thereof.

22. (Previously presented) The composition according to claim 17, wherein the concentration of human growth hormone (hGH) in said composition is between 0.1 and 100 mg/ml.

23.-62. (Canceled)

63. (Currently amended) The polyarginine complexed containing human growth hormone (hGH) crystal according to claim 4, 7, 8 or 9, wherein the complexed crystal is produced by:

- (a) crystallizing the hGH human growth hormone, and
- (b) complexing polyarginine to the crystallized hGH human growth hormone.

64. (Currently amended) The polyarginine complexed-containing hGH crystal according to claim 4, further comprising a cation.

65. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 4.

66. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 7.

67. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 8.

68. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 9.

69.-71. (Canceled)

72. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 63.

73. (Currently amended) A pharmaceutical composition comprising the polyarginine complexed-containing hGH crystal of human growth hormone of claim 64.

74. (Currently amended) The polyarginine complexed containing hGH crystal according to claim 7, further comprising a cation.

75. (Currently amended) The polyarginine complexed containing hGH crystal according to claim 8, further comprising a cation.

76. (Currently amended) The polyarginine complexed containing hGH crystal according to claim 9, further comprising a cation.

77.-79. (Canceled)

80. (Currently amended) The polyarginine complexed containing hGH crystal according to claim 63, further comprising a cation.

81.-84. (Canceled)